

Attorney Docket No.: DEX-0188
Inventors: Roberto Macina
Serial No.: 09/806,301
Filing Date: July 27, 2001
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REMARKS

Claims 1-10 are pending in the instant application. Claims 7-10 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicant in this amendment. Claims 1-6 have been rejected. Claim 1 has been amended and claims 2-6 have been canceled. Support for these amendments is provided in the specification at page 5, line 29, through page 6, line 2, page 9, lines 6-14 and pages 24-25. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed August 13, 2003. Accordingly, in an earnest effort to advance the prosecution, Applicant has canceled claims 7-10 without prejudice. Further, Applicant has amended claim 1 per the Examiner's request to reflect that the method is drawn to measurement of ESBPII polypeptides.

II. Information Disclosure Statement

Applicants are providing herewith copies of references AQ, AZ-BL, BN-BS, BU, BV and BX-CB cited and provided with the IDS

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filed by Applicants on April 29, 2002. Consideration and entry of these references into the record is respectfully requested.

III. Rejection of Claims 1-5 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner suggests that the specification fails to describe a representative number of species of the genus of ESBPII polypeptides or structural or functional features common to the member of the genus.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicant has amended claim 1 in accordance with teachings of the specification at page 5, line 29 through page 6, line 2, and page 9, lines 6-14, to state that the polypeptide is encoded by SEQ ID NO:1 or comprises SEQ ID NO:2. This amendment makes clear structural features of the ESBPII polypeptide.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is therefore respectfully requested.

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**IV. Rejection of Claims 1-6 under 35 U.S.C. § 112, first
paragraph - Lack of Enablement**

Claims 1-6 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner has acknowledged the specification to be enabling for diagnosis of breast cancer. However, the Examiner suggests that the specification does not reasonably provide enablement for diagnosis of prostate cancer or any gynecologic cancer; or for the diagnosis of metastasis, for monitoring of change in stage, or the monitoring of the onset of metastasis of prostate cancer or any gynecologic cancer.

Applicant respectfully traverses this rejection.

Table 2 of the instant specification and pages 24 through 25 of the instant specification teach that ESBPII is overexpressed in 50% of uterine cancer samples tested, that median expression in the ovary cancer samples is four times higher than the median expression in the normal ovary samples and that the median expression in the prostate cancer samples is higher than the median expression in the normal prostate samples. These data are similar to data presented for breast cancer in the instant specification, which has been acknowledged to be enabled by the Examiner. Accordingly, these data, indicative of ESBPII being a

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marker for detecting the presence of ovarian, uterine and prostate cancer should also be accepted as enabling for these cancers.

In an earnest effort to advance the prosecution of this case and in accordance with teachings at pages 24 through 25 of the instant specification, Applicant has amended claim 1 to specify that the method is for detecting prostate cancer, ovarian cancer or uterine cancer. Further, Applicant has canceled claims 2-5, thus mooting the Examiner's remarks with respect to enablement of methods of staging and monitoring cancer and metastases thereof.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested in light of the amendments to the claims and the above remarks.

V. Rejection of Claims 1 and 6 under 35 U.S.C. § 102(e)

Claim 1 has been rejected under 35 U.S.C. § 102(e) as being anticipated by Watson (U.S. Patent 6,566,072). The Examiner suggests that Watson teaches a method for detecting the presence of breast cancer, comprising measuring levels of mammoglobin, a protein that is closely related to a protein having the amino acid sequence of SEQ ID NO:2.

Claims 1 and 6 have also been rejected under 35 U.S.C. §

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102(e) as being anticipated by Billing-Medel (U.S. Patent 6,183,952). The Examiner suggests that Billing-Medel teaches methods for diagnosing the presence of breast cancer comprising measuring a protein having the sequence of SEQ ID NO:2.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to specify that the cancer detected is ovarian, uterine or prostate cancer. Support for this amendment is provided in the specification at page 5, lines 21-23, and page 25, lines 1-18. Thus, no new matter is added by this amendment.

As neither of the cited references teach detecting the presence of prostate, uterine or ovarian cancer with ESBPII, these references can not anticipate the claims as amended.

Withdrawal of these rejections under 35 U.S.C. § 102(e) is therefore respectfully requested.

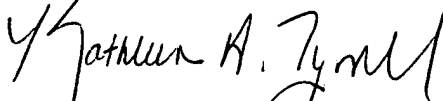
VI. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

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favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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